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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,705	09/07/2000	Magnus Bjorsne	3525-95	6406

7590 03/25/2003

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EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 03/25/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,705

Applicant(s)

BJORSNE ET AL.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 19-27 is/are pending in the application.
- 4a) Of the above claim(s) 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 19, 20 and 27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

Detailed Action

The 112, second paragraph rejection of claim 20, claim 1, part c, is withdrawn in light of applicant's amendment and remarks at paper. no. 19. The Restriction at paper no. 9 is FINAL.

(old objections and rejections)

1. Applicant is advised that should claim 1 be found allowable, claim 15 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

2. Applicant is advised that should claim 1 be found allowable, claim 16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim(s) 1, 3-13, 19-20 in part are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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A. In claim 1, lines 22-23, page 74, and all other occurrences throughout claims 3-20, the phrase "(in which latter three groups" is indefinite. The phrase "A represents a single bond, C1-6 alkylene... -OH groups);" between lines 21-24 on page 74, should be rewritten in the form " A is ____, ____, or ____, or ____, ____, and ____ which are optionally substituted with A and B, or ____ and ____ which are attached to the bispidine nitrogen..."

B. In claim 11, line 3, page 60, the phrase "in which latter two cases p is 1, 2, or 3)" is indefinite. The term "wherein" is suggested.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-13, 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable Lubisch et. al. . (See Reference N, EP 0308843).

Lubisch et. al. teaches the instant compound as shown in Formula I, where R is halogen, C1-C4 alkoxy, R1 is Halogen, C1-C4 alkoxy, Z is C1-C4 alkylene, R3 is H, C1-C4 alkyl, and R5 is C1-C4 alkyl. At page 5, rightmost column, lines 30-35, see formula I. The difference between the prior art compound and the instantly claimed compounds is the teaching of a generic compound versus a disclosed species. It would have been obvious to one of ordinary skill in the art to select various known radicals within a genus to prepare structurally similar compounds. Accordingly, the compounds are deemed

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unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13, 19-20, and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not provide enablement for R1 equal to all-CH₂)a-Het1 optionally substituted by one or more substituents selected from the group consisting of -OH, halo, cyano, nitro, C1-4 alkyl and C1-4 alkoxy, wherein Het1 equals all five to ten-membered heterocyclic ring containing one or more heteroatoms selected from the group consisting of oxygen, nitrogen and sulfur and which also optionally includes one or more =O substituents; R9 equal to all -(CH₂)d-Het2, optionally substituted by one or more substituents selected from the group consisting of -OH, halo, cyano, nitro, C1-4alkyl, C(O)R13, C(O)OR14 and -N(H)S(O)R15, and aryl or -(CH₂)-aryl which can be optionally substituted by one or more substituents selected from halo, nitro, C1-6 alkyl, and C1-6 alkoxy, or Het2 and R12 -R20 equal to Het3 which can equal all five to ten-membered heterocyclic rings containing one or more heteroatoms selected from the group consisting of -OH, cyano, halo, amino, nitro, C1-6 alkyl (optionally terminated by N(H)C(O)OR20a), C1-6 alkoxy, -C(O)N(H)R21, -N(H)S(O)2R23 and -OS(O)2R24, Het 4 equaling all five to ten-membered heterocyclic rings containing one or more

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heteroatoms selected from the group consisting of oxygen, nitrogen and sulfur, and which also optionally includes one or more =O substituents, A, where in the latter three groups of the substituents it can represent, the $-(CH_2)_m-$ group is attached to the bispidine nitrogen atom and which latter four groups are optionally substituted by one or more $-OH$ groups. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement. Heteroaryl or aryl rings cannot support electron-withdrawing groups such as cyano or nitro in the ortho or meta position, although the applicant claims that Het1, Het2, and aryl moieties can be substituted by one or more electron withdrawing groups. The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in *Ex parte* Foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation

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needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of breadth of the claims, R1, Het1-Het4, A, and aryl, encompass a much wider Markush grouping of radicals than those radicals tested. In terms of the nature of the invention, these compounds are useful in the treatment of cardiac arrhythmias. In terms of the fifth Wands factor, the level of predictability in the art is low since these compounds are not tested for their effects on the actual diseases claimed. In terms of the sixth Wands factor the amount of direction provided by the inventor is poor, because the applicant does not conduct tests for any compounds where the radicals can be the Het1-Het4 moieties claimed, or for A, where in the latter three groups of the substituents it can represent, the $-(CH_2)_m-$ group is attached to the bispidine nitrogen atom and which latter four groups are optionally substituted by one or more $-OH$ groups. In terms of the seventh Wands factor, the applicant does not have examples where radicals can be the Het1-Het4 moieties claimed, or for A, where in the latter three groups of the substituents it can represent, the $-(CH_2)_m-$ group is attached to the bispidine nitrogen atom and which latter four groups are optionally substituted by one or more $-OH$ groups. In terms of the 8th Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

The elected species appears to be allowable.

Response to Applicant's Remarks

103 (a) rejection

The applicant asserts that the EP 308843 reference and the Beller reference describe only compounds that are unsubstituted at the 2, 4, and 6 positions of the bispidine ring. However, Lubisch claims a compound of formula I where R³ can be alkyl in the 2, 4, or 6 positions. See the compound of formula I at page 5, rightmost column, lines 30-35.

112, first paragraph rejection

The applicant alleges that the examiner has not provided any basis as to why one skilled in the art would be unable to prepare and use all of the compounds falling within the scope of the claims. However, the examiner mentioned numerous examples of how the applicant's invention violated the Wands factors. R¹, Het1-Het4, A, and aryl encompass a much wider Markush grouping of radicals than those radicals tested. In terms of the nature of the invention, these compounds are useful in the treatment of cardiac arrhythmias. The level of predictability in the art is low since these compounds are not tested for their effects on the actual diseases claimed. In terms of the sixth Wands factor the amount of direction provided by the inventor is poor, because the applicant does not conduct tests for any compounds where the radicals can be the Het1-Het4 moieties claimed, or for A, where in the latter three groups of the substituents it can represent, the $-(CH_2)_m-$ group is attached to the bispidine nitrogen atom and which latter four groups are optionally substituted by one or more $-OH$ groups. The

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applicant does not have examples where radicals can be the Het1-Het4 moieties claimed, or for A, where in the latter three groups of the substituents it can represent, the $-(CH_2)_m$ - group is attached to the bispidine nitrogen atom and which latter four groups are optionally substituted by one or more $-OH$ groups.

112, second paragraph rejection

The applicant asserts that it is not understood why the examiner persist with the rejection of the phrase "which latter three groups". The applicant's allege that this phrase refers to the previous three groups mentioned and that this is clear. However, the term "latter" is indefinite and ambiguous language. It is not clear that this phrase is describing the three previous groups since the phrase is enclosed in parenthesis and since the phrase uses the term "latter."

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

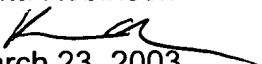
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson


March 23, 2003



ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
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